APR - 9 2012

K112481 1/2

INTEGRA
LIMIT UNCERTAINTY

Summary of Safety and Effectiveness

Sponsor:

Ascension Orthopedics
8700 Cameron Road
Austin, TX 78754-3832

Contact Person:

Bradley W. Strasser
Senior Analyst, Regulatory Affairs
512-836-5001 ext. 1541

Date:

06 April 2012

Trade Name:

First Choice® Partial Ulnar Head Implant

Common Name:

Ulnar Head Prosthesis

Product Code:

KXE – Prosthesis, Wrist, Hemi-, Ulnar

Classification:

21 CFR §888.3810 – Wrist joint ulnar (hemi-wrist) polymer prosthesis

Panel:

Orthopedic

Predicate Device:

Ascension® Modular Ulnar Head (MUH); K052137, cleared 03 November 2005; manufactured by Ascension Orthopedics, Inc.

Device Description:

The *First Choice* Partial Ulnar Head implant is a one-piece hemi-arthroplasty device intended to replace the articulating surface of the distal ulnar head. It is constructed from cobalt chromium alloy and replaces the ulnar head while retaining the ulnar neck and styloid. The distal head is polished to a mirror finish for articulation within the distal radioulnar joint and the proximal stem has a roughened grit-blasted surface for uncemented press-fit fixation in the ulnar medullary canal. The *First Choice* Partial Ulnar Head implant is available in 12 sizes.

Intended Use:

The *First Choice* Partial Ulnar Head implant is intended for partial replacement of the distal ulna for rheumatoid, degenerative, or post-traumatic arthritis presenting with pain and weakness localized to the

distal radioulnar joint and not improved by conservative treatment.

The *First Choice* Partial Ulnar Head implant is intended for press-fit use.

Basis of Substantial Equivalence:

The *First Choice* Partial Ulnar Head implant is similar to the *First Choice* Modular Ulnar Head implant in terms of intended use and fundamental scientific technology. Performance data demonstrates that the subject device design is substantially equivalent to the predicate in terms of strength and function.

Non-Clinical Performance Data:

The following non-clinical tests and analyses were conducted to support substantial equivalence of the *First Choice* Partial Ulnar Head implant to the predicate Modular Ulnar Head implant:

- Ulnar Head Biomechanics
- DRUJ Stem Bend Strength

Clinical Performance Data:

Clinical performance data were not necessary to support substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ascension Orthopedics
% Mr. Bradley W. Strasser
8700 Cameron Road
Suite 100
Austin, TX 78754-3832

APR - 9 2012

Re: K112481
Trade/Device Name: First Choice Partial Ulnar Head Implant
Regulation Number: 21 CFR 888.3810
Regulation Name: Wrist joint ulnar (hemi-wrist) polymer prosthesis
Regulatory Class: II
Product Code: KXE
Dated: March 2, 2012
Received: March 5, 2012

Dear Mr. Strasser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

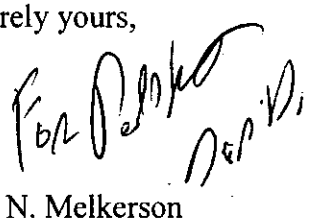
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112481

Device Name:

First Choice® Partial Ulnar Head Implant

Indications for Use:

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The *First Choice* Partial Ulnar Head implant is intended for press-fit use.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112481